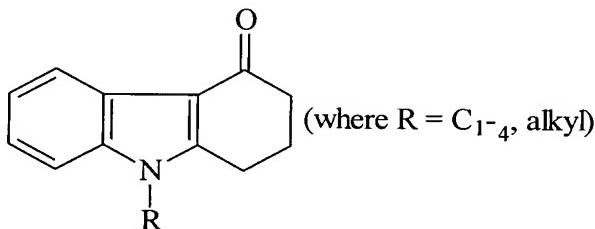


Amendment to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

In the Claims:

- Claim 1 (currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.0%.
- Claim 2 (currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.5%.
- Claim 3 (currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.9%.
- Claim 4 (withdrawn) A process for preparing dimethylamino-methyl-carbazolone comprising the steps of:
a) preparing a solution of methyl-carbazolone having the formula:



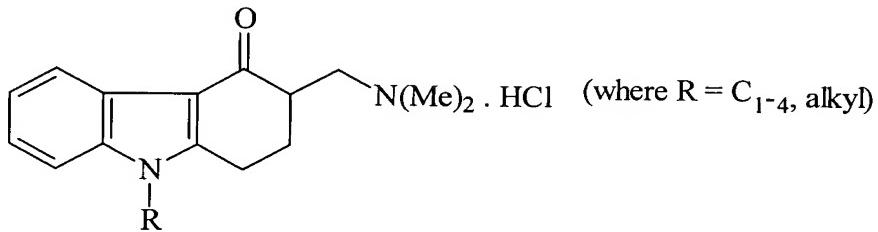
- b) heating the solution in the presence of dimethylamine hydrochloride and paraformaldehyde;
c) basifying the solution to form a precipitate;
d) separating the precipitate from the solution;
e) drying the precipitate.

- Claim 5 (withdrawn) The process according to claim 4, wherein R is methyl.
- Claim 6 (withdrawn) The process according to claim 4, wherein the heating step is performed at a temperature of about 70⁰C to about 100⁰C.
- Claim 7 (withdrawn) The process according to claim 4, wherein the heating step is performed at a temperature of about 80⁰C to about 90⁰C.
- Claim 8 (withdrawn) The process according to claim 4, wherein the heating step is performed for about 6 to about 24 hours.

- Claim 9 (withdrawn) The process according to claim 4, wherein the heating step is performed for about 6 to about 12 hours.
- Claim 10 (withdrawn) The process according to claim 4, wherein the heating step is performed in acetic acid.
- Claim 11 (withdrawn) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 1.1 to about 1.5 equivalents of dimethylamine hydrochloride and paraformaldehyde.
- Claim 12 (withdrawn) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 1.2 equivalents of dimethylamine hydrochloride and formaldehyde.
- Claim 13 (withdrawn) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 1.1 to about 1.5 equivalents of dimethylamine hydrochloride and formaldehyde.
- Claim 14 (withdrawn) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 1.2 equivalents of dimethylamine hydrochloride and formaldehyde.
- Claim 15 (withdrawn) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 4 to about 6 volumes of acetic acid.
- Claim 16 (withdrawn) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 4 volumes of acetic acid.
- Claim 17 (withdrawn) The process according to claim 4, wherein the solution of methyl-carbazolone is basified by about 45% sodium hydroxide.
- Claim 18 (withdrawn) The process according to claim 17, wherein the solution is basified to a pH of about 13 to about 14.
- Claim 19 (withdrawn) The process according to claim 17 or 18, wherein the basifying step is performed in the presence of 10% celite.

Claim 20 (withdrawn) A process for preparing ondansetron base, comprising the steps of:

- a) preparing a solution of methyl-imidazole and dimethylamino-methyl-carbazolone of the formula



- b) heating the solution;
c) removing a precipitate containing ondasetron base from the solution;
d) washing the precipitate;
e) drying precipitate to obtain ondansetron base.

Claim 21 (withdrawn) The process according to claim 20, wherein the solution is prepared by adding about 4 to about 6 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

Claim 22 (withdrawn) The process according to claim 20, wherein the solution is prepared by adding about 5 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

Claim 23 (withdrawn) The process according to claim 20, wherein the solution is prepared in the presence of 10% celite.

Claim 24 (withdrawn) The process according to claim 20, further comprising the step of: recrystallizing ondansetron base.

Claim 25 (withdrawn) The process according to claim 24, wherein the recrystallizing step is performed in the presence of activated carbon and methanol.

Claim 26 (withdrawn) A process of preparing pure ondansetron hydrochloride dihydrate comprising the steps of:

- a) preparing a solution of ondansetron base;
b) acidifying the solution with hydrogen chloride to form a precipitate;
c) washing the precipitate; and

- d) crystallizing pure ondansetron hydrochloride dihydrate.
- Claim 27 (withdrawn) The process according to claim 26 wherein about 3 to about 7 volumes of water is added to ondansetron base to prepare a solution of ondansetron base.
- Claim 28 (withdrawn) The process according to claim 26 wherein about 5 volumes of water is added to ondansetron base to prepare a solution of ondansetron base.
- Claim 29 (withdrawn) The process according to claim 26 wherein about 1.0 to about 1.4 equivalents of about 32% (v:v) hydrochloric acid is added to acidify the solution to induce precipitation.
- Claim 30 (withdrawn) The process according to claim 26 wherein about 1.1 equivalents of about 32% (v:v) hydrochloric acid is added to acidify the solution to induce precipitation.
- Claim 31 (withdrawn) The process of claims 29 or 30, wherein the solution is acidified to a pH about 1 to about 4.
- Claim 32 (withdrawn) The process of claims 29 or 30, wherein the solution is acidified to a pH about 3.
- Claim 33 (withdrawn) The process according to claim 26, wherein the precipitate is washed with about 5 to about 15 ml of isopropanol.
- Claim 34 (withdrawn) The process according to claim 26, wherein the precipitate is washed with about 10 ml of isopropanol.
- Claim 35 (withdrawn) The process according to claim 26, wherein the crystallizing step is achieved by adding about 3 to about 5 volumes of water to induce crystallization.
- Claim 36 (withdrawn) The process according to claim 26, wherein the crystallizing step is achieved by adding about 4 volumes of water to induce crystallization.
- Claim 37 (withdrawn) The process according to claim 26, wherein the crystallization step is repeated two times.

- Claim 38 (withdrawn) The process according to claim 26, wherein the crystallizing step is achieved in the presence of activated carbon.
- Claim 39 (withdrawn) The process according to claim 36, wherein the activated carbon is selected from the group consisting of SX-2, CA-1,CXV and SX-1.
- Claim 40 (withdrawn) The process according to claim 39, wherein the activated carbon is about 5 to about 15% SX-1.
- Claim 41 (withdrawn) The process according to claim 39, wherein the activated carbon is about 5 to about 10% SX-1.
- Claim 42 (original) Ondansetron hydrochloride dihydrate as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.0%.
- Claim 43 (original) Ondansetron hydrochloride dihydrate as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate have a purity of at least about 99.5%.
- Claim 44 (original) Ondansetron hydrochloride dihydrate as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.9%.
- Claim 45 (original) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.0%.
- Claim 46 (original) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.5%.
- Claim 47 (original) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.9%.